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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,014	04/20/2005	Magnus Ingelman-Sundberg	25401-40	8991

24256 7590 04/19/2007

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EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,014	INGELMAN-SUNDBERG ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) *1-10* is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1. Claims 1-3, drawn to a binding agent or an antibody to CYP2W1 or SEQ ID NO:8.

Groups 2-4. Claim 4, drawn to a method for treating lung, colon, or ovarian tumor, using CYP2W1 protein. A method treating each cancer constitutes a single, distinct invention.

Groups 5-7. Claim 4, drawn to a method for treating lung, colon, or ovarian tumor, using CYP2W1 nucleic acid. A method treating each cancer constitutes a single, distinct invention.

Group 8. Claims 5-6, drawn to a method for screening agent that modulates CYP2W1 protein.

Group 9. Claims 5-6, 10, drawn to a method for screening agent that modulates CYP2W1 nucleic acid, or genes regulated by CYP2W1 promoter.

Groups 10-12. Claim 7, drawn to a method for treating lung, colon, or ovarian cancer, using a substance activated by CYP2W1 protein. A method treating each cancer constitutes a single, distinct invention.

Groups 13-15. Claim 7, drawn to a method for treating lung, colon, or ovarian cancer, using an inducer of CYP2W1 protein. A method treating each cancer constitutes a single, distinct invention.

Groups 16-18. Claim 7, drawn to a method for treating lung, colon, or ovarian cancer, using binding agent of CYP2W1 protein. A method treating each cancer constitutes a single, distinct invention.

Groups 19-21. Claim 7, drawn to a method for treating lung, colon, or ovarian cancer, using a combination of a substance activated by CYP2W1 protein, and an inducer of CYP2W1 protein, or a combination of a substance activated by CYP2W1 protein, an inducer of CYP2W1 protein, and a binding agent for CYP2W1 protein. A method treating each cancer constitutes a single, distinct invention.

Group 22. Claims 8-9, drawn to a DNA molecule, SEQ ID NO:10.

The inventions are distinct, each from the other because of the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or correponding techinical feature is a contribution over the prior art. The inventions listed as groups 1-22 do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of group I, an antibody binding specifically to CYP2W1 protein, or SEQ ID NO:8, is shown to be the same as the antibody taught by WO 200290521-A2 (Becha et al), or WO 200259260 A2 (Asundi et al), as evidenced by Banki et al, 1994, JBC, 269 (4): 2847-51, or Bendayan et al, 1995, J Histochem Cytochem,

43(9): 881-886. Thus the invention of group I lacks novelty and does not make a contribution over the prior art.

WO 200290521-A2 teaches an antibody to the disclosed polypeptide, which is a human drug metabolizing enzyme (items 6, 14). The polypeptide taught by WO 200290521-A2 is 87% similar to SEQ ID NO:8, from amino acid 1 to amino acid 431 (MPSRCH search result, 2007, us-10-532-014.rag, result 2, pages 1-2).

```
MPSRCH search result, 2007, us-10-532-014.8.rag.

RESULT 2
AAE33381
ID   AAE33381 standard; protein; 464 AA.
XX
AC   AAE33381;
XX
DT   02-APR-2003  (first entry)
XX
DE   Human DME-7 protein.
XX
KW   Human; drug metabolizing enzyme; DME; gastrointestinal disorder; asthma;
KW   peptic oesophagitis; peptic ulcer; Crohn's disease; autoimmune disorder;
KW   liver disorder; acquired immune deficiency syndrome; cataract; anaemia;
KW   inflammatory disorder; developmental disorder; achondroplastic dwarfism;
KW   Cushing's syndrome; endocrine disorder; diabetes insipidus; leukaemia;
KW   Sheehan syndrome; hypothyroidism; metabolic disorder; Addison's disease;
KW   glycogen storage disease; hypocalcaemia; conjunctivitis; pancreatitis;
KW   adenocarcinoma; cell proliferative disorder; actinic keratosis; cancer;
KW   arteriosclerosis; gene therapy; protein replacement therapy; lymphoma;
KW   eye disorder; sarcoma; obesity; melanoma; myeloma; AIDS; gout.
XX
OS   Homo sapiens.
XX
FH   Key             Location/Qualifiers
FT   Peptide         1. .28
FT                   /label= Signal_peptide
FT   Peptide         1. .24
FT                   /label= Signal_peptide
FT   Peptide         1. .22
FT                   /label= Signal_peptide
FT   Peptide         1. .20
FT                   /label= Signal_peptide
FT   Domain          4. .21
FT                   /note= "Transmembrane domain"
FT   Protein         21. .464
FT                   /note= "Mature human DME protein"
FT   Protein         23. .464
```

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FT                   /note= "Mature human DME protein"
FT   Protein         23. .464
FT                   /note= "Mature human DME protein"
FT   Protein         25. .464
FT                   /note= "Mature human DME protein"
FT   Domain          194. .222
FT                   /note= "Transmembrane domain"
XX
PN   WO200290521-A2.
XX
PD   14-NOV-2002.
XX
PF   10-MAY-2002; 2002WO-US015052.
XX
PR   10-MAY-2001; 2001US-0290430P.
PR   08-JUN-2001; 2001US-0296880P.
PR   22-JUN-2001; 2001US-0300472P.
PR   29-JUN-2001; 2001US-0301794P.
XX
PA   (INCY-) INCYTE GENOMICS INC.
XX
PI   Ring HZ, Hafalia AJA, Sanjanwala MM, Yao MG, Zebarjadian Y;
PI   Edwards CM, Yue H, Tang YT, Lee EA, Emerling BM, Warren BA, Lal
PG;
PI   Nguyen DB, Thangavelu K, Becha SD, Huang J, Ding L, Li JX;
PI   Griffin JA, Forsythe IJ, Richardson TW;
XX
DR   WPI; 2003-111969/10.
DR   N-PSDB; AAD51048.
XX
PT   New human drug metabolizing enzyme proteins and polynucleotides, useful
PT   for diagnosing, treating or preventing gastrointestinal (e.g. Crohn's
PT   disease) or autoimmune/inflammatory disorders (e.g. AIDS),
hypothyroidism
PT   or cancer.
XX
PS   Claim 1; Page 158-159; 175pp; English.
XX
CC   The invention relates to human drug metabolizing enzyme (DME) proteins
CC   and nucleic acid molecules encoding such proteins. Sequences of the
CC   invention are useful for diagnosing, treating or preventing
CC   gastrointestinal disorders (e.g. peptic oesophagitis, peptic ulcer or
CC   Crohn's disease) including liver disorders, autoimmune/inflammatory
CC   disorders (e.g. acquired immune deficiency syndrome; AIDS, anaemia,
CC   asthma, gout, pancreatitis or Crohn's disease), developmental disorders
CC   (e.g. Cushing's syndrome or achondroplastic dwarfism), endocrine
CC   disorders (e.g. Sheehan syndrome, diabetes insipidus or hypothyroidism),
CC   eye disorders (e.g. conjunctivitis or cataract), metabolic disorders
CC   (e.g. Addison's disease, glycogen storage diseases, hypocalcaemia or
CC   obesity) or cell proliferative disorders (e.g. actinic keratosis,
CC   arteriosclerosis or cancers including adenocarcinoma, leukaemia,
CC   lymphoma, melanoma, myeloma, sarcoma or bone, ovary, lung, breast,
CC   prostate or skin cancer). The present sequence is human DME protein
XX
```

SQ Sequence 464 AA;

Query Match 87.8%; Score 2249; DB 6; Length 464;
Best Local Similarity 99.5%; Pred. No. 6.1e-211;
Matches 429; Conservative 2; Mismatches 0; Indels 0; Gaps 0;

```
Qy          1 MALLLLLFLGLLGLWGLLCACAQDPSPAARWPPGPRPLPLVGNLHLLRLSQQDRSLMELS 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MALLLLLFLGLLGLWGLLCACAQDPSPAARWPPGPRPLPLVGNLHLLRLSQQDRSLMELS 60

Qy         61 ERYGPVFTVHLGRQKTVVLTGFEAVKEALAGPGQELADRPPIAIFQLIQRGGGIFFSSGA
120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 ERYGPVFTVHLGRQKTVVLTGFEAVKEALAGPGQELADRPPIAIFQLIQRGGGIFFSSGA
120

Qy        121 RWRAARQFTVRALHSLGVGREPVADKILQELKCLSGQLDGYRGRPFPLALLGWAPSNITF
180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 RWRAARQFTVRALHSLGVGREPVADKILQELKCLSGQLDGYRGRPFPLALLGWAPSNITF
180

Qy        181 ALLFGRRFDYRDPVFVSLLGLIDEVMVLLGSPGLQLFNVYPWLGALLQLHRPVLRKIEEV
240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 ALLFGRRFDYRDPVFVSLLGLIDEVMVLLGSPGLQLFNVYPWLGALLQLHRPVLRKIEEV
240

Qy        241 RAILRTLLEARRPHVCPGDPVCSYVDALIQQGQGDDPEGLFAEANAVACTLDMVMAGTET
300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 RAILRTLLEARRPHVCPGDPVCSYVDALIQQGQGDDPEGLFAEANAVACTLDMVMAGTET
300

Qy        301 TSATLQWAALLMGRHPDVQGRVQEELDRVLGPGRTPRLEDQQALPYTSAVLHEVQRFITL
360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 TSATLQWAALLMGRHPDVQGRVQEELDRVLGPGRTPRLEDQQALPYTSAVLHEVQRFITL
360

Qy        361 LPHVPRCTAADTQLGGFLLPKGTPVIPLLTSVLLDETQWQTPGQFNPGHFLDANGHFVKR
420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 LPHVPRCTAADTQLGGFLLPKGTPVIPLLTSVLLDETQWQTPGQFNPGHFLDANGHFVKR
420

Qy        421 EAFLPFSAGRR 431
              |||||||||::
Db        421 EAFLPFSAGQQ 431
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WO 200259260 A2 teaches an antibody to the disclosed polypeptide. The polypeptide taught by WO 200290521-A2 is 75% similar to SEQ ID NO:8, from amino acid 57 to amino acid 431 (MPSRCH search result, 2007, us-10-532-014.rag, result 5, pages 2-4).

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MPSRCH search result, 2007, us-10-532-014.8.rag

RESULT 5
ABP64996
ID   ABP64996 standard; protein; 408 AA.
XX
AC   ABP64996;
XX
DT   25-FEB-2003  (first entry)
XX
DE   Human protein SEQ ID 656.
XX
KW   Human; expressed sequence tag; EST; haematopoietic disorder;
KW   central nervous system disease; viral infection;
KW   peripheral nervous system disease; non-healing wound; infectious
disease;
KW   immune deficiency; immune disorder; bacterial infection; allergy;
cancer;
KW   fungal infection; autoimmune disorder; coagulation disorder; nootropic;
KW   antiallergic; antiinflammatory; immunosuppressive; neuroprotective;
KW   cytostatic; haemostatic; virucide; antibacterial; fungicide;
KW   immunostimulant; cerebroprotective.
XX
OS   Homo sapiens.
XX
PN   WO200259260-A2.
XX
PD   01-AUG-2002.
XX
PF   16-NOV-2001; 2001WO-US042950.
XX
PR   17-NOV-2000; 2000US-00714936.
XX
PA   (HYSE-) HYSEQ INC.
XX
PI   Tang YT, Goodrich RW, Liu C, Zhou P, Asundi V, Zhang J, Zhao QA;
PI   Ren F, Xue AJ, Yang Y, Wehrman T, Drmanac RT;
XX
DR   WPI; 2002-590824/63.
DR   N-PSDB; ABQ99582.
XX
PT   New isolated polynucleotide, useful in research, diagnostic or
PT   therapeutic methods, e.g. preventing or treating disorders involving
PT   aberrant protein expression or biological activity.
XX
```

PS Claim 20; SEQ ID NO 656; 394pp; English.
XX
CC The present invention relates to novel human coding sequences (ABQ99268-
CC ABQ99608) and proteins (ABP64682-ABP65022). The sequences are useful in
CC therapeutic, diagnostic and research methods. The polynucleotides may be
CC used in the field of molecular biology as hybridisation probes, primers
CC for PCR, for chromosome and gene mapping, for the recombinant production
CC of protein, or in generation of anti-sense DNA or RNA. The
CC polynucleotides are useful in diagnostics as expressed sequence tags
CC (ESTs) for identifying expressed genes or for physical mapping of the
CC human genome. The proteins may be used as molecular weight markers, or
as
CC nutritional sources or supplements. The proteins may be used to maintain
CC and expand cell population in a totipotential or pluripotential state
CC useful for re-engineering damaged or diseased tissues, transplantation,
CC manufacture of bio-pharmaceuticals or the development of bio-sensors.
The
CC polynucleotides and proteins are useful for preventing, treating or
CC ameliorating disorders involving aberrant protein expression or
CC biological activity, e.g. haematopoietic disorders, central/peripheral
CC nervous system diseases, mechanical and traumatic disorders, non-healing
CC wounds, immune deficiencies and disorders, infectious diseases caused by
CC viral, bacterial or fungal infection, autoimmune disorders, allergic
CC reactions and conditions, coagulation disorders, or cancer. The
CC polynucleotide sequences of the invention were assembled from ESTs
CC isolated mainly by sequencing by hybridisation, and in some cases,
CC sequences obtained from one or more public databases. Note: The sequence
CC data for this patent did not form part of the printed specification, but
CC was obtained in electronic format directly from WIPO at
CC ftp.wipo.int/pub/published_pct_sequences
XX
SQ Sequence 408 AA;

Query Match 75.9%; Score 1945; DB 5; Length 408;
Best Local Similarity 99.2%; Pred. No. 3.2e-181;
Matches 372; Conservative 3; Mismatches 0; Indels 0; Gaps
0;

```
Qy          57 MELSERYGPVFTVHLGRQKTVVLTGFEAVKEALAGPGQELADRPPIAIFQLIQRGGGIFF
116
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db           1 MELSERYGPVFTVHLGRQKTVVLTGFEAVKEALAGPGQELADRPPIAIFQLIQRGGGIFF 60

Qy         117 SSGARWRAARQFTVRALHSLGVGREPVADKILQELKCLSGQLDGYRGRPFPLALLGWAPS
176
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          61 SSGARWRAARQFTVRALHSLGVGREPVADKILQELKCLSGQLDGYRGRPFPLALLGWAPS
120

Qy         177 NITFALLFGRRFDYRDPVFVSLLGLIDEVMVLLGSPGLQLFNVYPWLGALLQLHRPVLRK
236
               |||||||||||||||||||||||||||||||||||||||||||:||||||||||||||||
Db         121 NITFALLFGRRFDYRDPVFVSLLGLIDEVMVLLGSPGLQLFNVHPWLGALLQLHRPVLRK
180
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```
Qy        237 IEEVRAILRTLLEARRPHVCPGDPVCSYVDALIQQGQGDDPEGLFAEANAVACTLDMVMA
296
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 IEEVRAILRTLLEARRPHVCPGDPVCSYVDALIQQGQGDDPEGLFAEANAVACTLDMVMA
240

Qy        297 GTETTSATLQWAALLMGRHPDVQGRVQEELDRVLGPGRTPRLEDQQALPYTSAVLHEVQR
356
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 GTETTSATLQWAALLMGRHPDVQGRVQEELDRVLGPGRTPRLEDQQALPYTSAVLHEVQR
300

Qy        357 FITLLPHVPRCTAADTQLGGFLLPKGTPVIPLLTSVLLDETQWQTPGQFNPGHFLDANGH
416
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 FITLLPHVPRCTAADTQLGGFLLPKGTPVIPLLTSVLLDETQWQTPGQFNPGHFLDANGH
360

Qy        417 FVKREAFLPFSAGRR 431
                ||||||||||||::
Db        361 FVKREAFLPFSAGQQ 375
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The antibody taught by the art would bind to SEQ ID NO:8, or CYP2W1, which is interpreted as a variant of SEQ ID NO:8, as evidenced by Banki et al, which teach that an antibody against human transaldolase could bind to yeast transaldolase which is about 58% homologous with human transaldolase, i.e. an antibody could cross-react and bind to a polypeptide at least with 58% homology to its antigen (abstract), or Bendayan et al, which teach that anti-human proinsulin monoclonal antibody to the Arg-Arg dipeptide, although providing very specific binding results, cross-reacts with non-related molecules, i.e., rat, bovine, porcine and human glucagons (abstract).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected

invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SHANON FOLEY can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
April 12, 2007

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600